



COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending for the 22nd time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates) and amending Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. INTRODUCTION AND CONTEXT

In 1997 Denmark and in 1998 Spain notified the Commission, in the framework of Directive 92/59/EEC¹ on general product safety, about health risks to small children through the release of phthalates from certain child-care articles and toys made of PVC and intended for mouthing. The phthalates are plasticisers used to soften the PVC. The Commission requested, in October 1997, the Commission's Scientific Committee on Toxicology and Ecotoxicology and the Environment (SCTEE) to give its opinion.

In a first opinion delivered in February 1998 (updated in April and June the same year) the SCTEE reviewed the risks posed by phthalates and established migration limits for phthalates in soft PVC toys. As a short term measure the Commission adopted a Recommendation in July 1998 (98/485/EC) based on the work of the Scientific Committee. The Recommendation concerns child care articles and toys intended to be placed in the mouth by young children of less than three years of age and made of soft PVC containing certain phthalates. Member States are asked to adopt the measures required to ensure a high level of child health protection taking into consideration the opinion of the SCTEE. The SCTEE delivered a new opinion based on the latest scientific information in November 1998 expressing « some concern » on the most commonly used phthalate (DINP), and « serious concern » on another one (DEHP). It was furthermore concluded that the use of these phthalates in toys put in the mouth by children, did not respect the recommended safety margin. Exposure to DINP and DEHP from other sources than soft PVC toys will, according to the Committee, increase the concern but the magnitude of such exposures is uncertain. The existence of such additional exposure should be taken into account in managing the risks in question.

Two approaches to reduce the risks to children of phthalates have been considered, i.e. to establish limits for migration of phthalates from toys and to ban the use of phthalates in toys. An approach based on migration limits requires testing methods to ensure compliance. However, the testing methods developed have, in a review by the SCTEE, not been found sufficiently good for regulatory purposes (opinion of 28 September 1999) which means that the approach based on migration limits is not possible at this time. The present proposal adopts the approach of a ban and stipulates that certain phthalates may not be used in toys and child care articles intended to be put in the mouth by children under the age of three. Furthermore, it is not allowed to place such products on the market if they contain certain phthalates. Other toys of soft PVC intended for children under the age of three and which could be put in the mouth, should bear a label alerting the caretakers to ensure that the children are not putting them in the mouth. This ban approach should provide a high level of safety to small children.

As the adoption and implementation of the proposed ban on phthalates under Directive 76/769 will, due to the decision-making arrangements applicable, take a certain period, it is also necessary, given the character of the risk, to ensure a consistent high level of child health protection during the period preceding this implementation. Therefore the Commission is simultaneously to agree a Commission Decision under Article 9 of the Directive on Product Safety 92/59/EEC requiring Member States to take temporary measures to implement the prohibition foreseen in the proposal under Directive 76/769 within less than 10 days.

¹ OJ L 228, 11.8.1992, p. 24.

However, the market situation must be continually monitored to ensure that any alternative products or substitute plasticisers do not introduce new health dangers. Member States will perform this monitoring and inform the Commission which will produce a report within three years of adoption of this Directive. The report will, together with other scientific information, serve as a basis for reviewing this Directive within four years of adoption and for considering possible restrictions on other substances.

2. JUSTIFICATION FOR PROPOSAL AND CONSIDERATIONS OF SUBSIDIARITY

What are the objectives of the proposal in relation to the Community's obligations ?

The objective of the proposal is to introduce harmonised provisions with regard to phthalates in toys and child care articles and thus preserving the Internal Market, as required by Article 95 of the Treaty. The objective is also, as set out in Article 95.3, Article 152.1 and 153.2 of the Treaty, to ensure a high level of health protection and of consumer protection, notably of young children.

Does the initiatives arise out of an exclusive Community competence or a shared competence?

The action to preserve the Internal Market for dangerous substances falls within the exclusive competence of the Community. This competence was established by Council Directive 76/769/EEC.

What are the courses of action available to the Community ?

The only course of action available that can provide a permanent solution is a proposal for an amendment to Directive 76/769/EEC, the twenty-second amendment, providing for harmonised rules on the marketing and use of phthalates in toys and child care articles².

Are uniform rules necessary ? Is it not sufficient to establish targets to be implemented by Member States ?

The proposed 22nd amendment establishes uniform rules for the marketing and use of phthalates in toys and child care articles. It also guarantees a high level of protection of health and safety of consumers. The proposed 22nd amendment is the only way to meet these goals. Targets would be insufficient.

3. RATIONALE OF THE PROPOSAL

Phthalates may pose a risk when used in soft PVC toys and child care articles put in the mouth by small children. The proposed 22nd amendment would prohibit the placing on the market of toys and child care articles intended to be put in the mouth by children under the age of three and containing phthalates. Furthermore, other toys of soft PVC intended for children under the age of three and which could be put in the mouth should bear a label alerting those caring for the children that the toys and child care articles are not to be put in the mouth.

² The solution for the transitional period pending application of this proposal is a phthalates ban under the General Product Safety Directive.

4. COSTS AND BENEFITS

4.1. Costs

A majority of Member States has introduced or notified their intention to introduce, in the framework of Commission Recommendation 98/485/EC, national bans, with various scopes, on the use of phthalates in toys. The Recommendation urges Member States to adopt the measures required to ensure a high level of health protection for children in regard to toys and child care articles made of soft PVC containing certain phthalates and intended to be put in the mouth by children of less than three years of age. The industry has adapted to this situation and, at least in a majority of Member States, most of the products in question no longer contain phthalates which means that the costs are likely to be limited.

4.2. Benefits

A benefit of the proposal is to protect the health of children. The proposed ban will ensure that no toys and child care articles containing phthalates are placed on the market if intended to be put in the mouth by children under the age of three. A second benefit is that the proposed Directive will provide harmonised provisions throughout the Community thus establishing an Internal Market in this field.

5. PROPORTIONALITY

The 22nd amendment would yield benefits in terms of protecting the health of children. This would be achieved at low costs.

6. CONSULTATIONS PERFORMED IN PREPARING THE DRAFT 22nd AMENDMENT

Advice on the preparation of the proposal was sought from experts from Member States, industry, (including manufacturers of chemicals, of PVC and of toys), and NGOs (environmental and consumer organisations) through meetings and a written procedure.

7. CONFORMITY WITH THE TREATY

This proposal is intended to facilitate a high level of protection of health of the consumers and is therefore in conformity with Article 95.3, 152.1 and 153.2 of the Treaty.

The proposal does not call for any special provisions of the kind referred to in Article 15 of the Treaty.

It is in conformity with Article 5.

8. CONSULTATION OF THE EUROPEAN PARLIAMENT AND THE ECONOMIC AND SOCIAL COMMITTEE

In compliance with Article 95 of the Treaty, the Co-decision Procedure with the European Parliament is applicable. The Economic and Social Committee has to be consulted.

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission³,

Having regard to the opinion of the Economic and Social Committee⁴,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

- (1) Article 14 of the Treaty establishes an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured.
- (2) Work on the internal market should improve the quality of life, health protection and consumer safety and the measures proposed by this Directive comply with the requirements that a high level of health protection and of consumer protection shall be ensured in the definition and implementation of all Community policies and activities.
- (3) The presence of phthalates in certain toys and childcare articles made of soft PVC and intended to be placed in the mouth, presents risks related to general toxicity to the health of young children.
- (4) The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), after being consulted by the Commission, has delivered two opinions on these health risks.
- (5) The Commission Recommendation 98/485/EC on childcare articles and toys intended to be placed in the mouth by children of less than three years of age, made of soft PVC

³ OJ
⁴ OJ

containing certain phthalates⁵ invites Member States to take measures required to ensure a high level of child health protection in regards to these products.

- (6) Limitations already adopted or planned by certain Member States on the marketing of toys and childcare articles because of their phthalate content directly affect the completion and functioning of the internal market and it is therefore necessary to approximate the laws of the Member States in this field and consequently to amend Annex 1 to Directive 76/769/EEC⁶.
- (7) It is necessary to provide for adequate labeling for child care articles made of soft PVC or including parts made of soft PVC intended for children under the age of three, which, although not intended for that purpose, can be put in the mouth. Such labeling also has to be provided for in Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys⁷ for those toys, which fall within the scope of that Directive.
- (8) The Commission will review the provisions in this Directive in the light of further scientific knowledge within four years of adoption.
- (9) This Directive does not affect Community legislation laying down minimum requirements for the protection of workers contained in Council Directive 89/391/EEC⁸ and in individual directives based thereon, in particular Council Directive 90/394/EEC⁹ and Council Directive 98/24/EC¹⁰ on protection of health and safety of workers from the risk related to chemical agents at work.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 76/769/EEC is hereby amended as set out in the Annex hereto.

Article 2

In Annex IV of Directive 88/378/EEC the following paragraph is added:

“7. Toys, made of or including parts of soft PVC containing the phthalates listed in point XX of the Annex to Directive 76/769/EEC, which are intended for children under the age of three and which can be put in the mouth, although not intended for that purpose

The following warning shall appear in an easily legible and indelible form on the packaging for the toy.

⁵ OJ L 217, 5.8.1998, p. 35-37

⁶ OJ L 262, 27.9.1976, p. 201. Directive as last amended by Commission Directive 1999/77/EC, OJ L 207, 6.8.1999, p. 18.

⁷ OJ L 187, 16.7.1988, p. 1. Directive as last amended by Council Directive 93/68/EEC, OJ L 220, 30.8.1993, p. 1.

⁸ OJ L 183, 29.06.1989, p. 1.

⁹ OJ L 196, 26.07.1990, p. 1.

¹⁰ OJ L 131, 5.5. 1998, p. 11

“Warning – do not put in the mouth for extended periods as could release phthalates dangerous to child health”.

The following shorter warning shall appear in an easily legible and indelible form on the toy:

“Not to be kept in the mouth”.

Article 3

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive no later than [six month] after the date of its entry into force. They shall forthwith inform the Commission thereof.

They shall apply these provisions [one year] after entry into force of this Directive.

2. When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

Article 4

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX

The following point is added to Annex I to Directive 76/769/EEC:

XX Phthalates

of the following types:

- di-“isononyl” phthalate (DINP)
CAS No 28553-12-0
EINECS No 249-079-5
- bis(2-ethylhexyl) phthalate (DEHP)
CAS No 117-81-7
EINECS No 204-211-0
- dioctyl phthalate (DNOP)
CAS No 117-84-0
EINECS No 204-214-7
- di-“isodecyl” phthalate (DIDP)
CAS No 26761-40-0
EINECS No 247-977-1
- benzyl butyl phthalate (BBP)
CAS No 85-68-7
EINECS No 201-622-7
- dibutyl phthalate (DBP)
CAS No 84-74-2
EINECS No 201-557-4

1. May not be used as substances or as constituents of preparations at concentrations of greater than 0.1% in toys and child care articles made of PVC, or including parts of PVC, intended to be put in the mouth by children under the age of three.

2. Products referred to in point 1 above may not be placed on the market unless they conform to the requirements stated.

3. The following warning shall appear in an easily legible and indelible form on the packaging for childcare articles, other than those referred to in point 1 above, made of or including parts of soft PVC containing one or more of these phthalates, and intended for children under the age of three and which can be put in the mouth:

“Warning – do not put in mouth for extended periods as could release phthalates dangerous to child health”.

The following shorter warning shall appear in an easily legible and indelible form on the childcare article:

“Not to be kept in the mouth”.